

REMARKS

Claims 1-83 were in the originally filed application. Claims 1-43, 46-58, and 62-83 were previously withdrawn as being directed to a non-elected invention and claim 61 was previously cancelled. Claims 45, 59 and 60 were previously presented, and claim 44 is amended herein. Applicants respectfully request reconsideration of the claims in light of the following arguments. Applicants believe that the application is in a condition for allowance.

Claim Rejections

Claims 44, 45, 59, and 60 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicant respectfully traverses this rejection. The courts have pointed out that “[n]ot every last detail [of an invention need] be described [in a specification], else patent specifications would turn into production specifications, which they were never intended to be.” *In re Gay*, 135 USPQ 311, 316 (C.C.P.A. 1962). Citing the opinion in *In re Gay*, the Board of Patent Appeals and Interferences echoed this point in its statement that “the law does not require a specification to be a blueprint to satisfy the requirement for enablement under 35 U.S.C. 112, first paragraph.” *Staehein v. Secher*, 24 USPQ2d 1513, 1516 (Bd. Pat. App. & Int. 1992).

Further, the MPEP states that “the specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

Applicant maintains that the pending claims are enabled by the specification and as such a person of ordinary skill in the art could practice the invention without undue experimentation. The specification provides the requisite teaching to show how the non-natural amino acid, polypeptides or protein is modified. The MPEP states that “the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the

art *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).” Moreover, the courts have noted that additional factors, such as teachings in references, will be available to substantiate any doubts that the asserted scope of enablement is in fact commensurate with the scope of protection sought. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513, (Fed. Cir. 1993); *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). Applicant maintains that the instant Specification satisfies the enablement requirement. Applicant submits that given the knowledge in the art and teachings in the references, and in view of the present specification, a person of ordinary skill in the art would be able to make and use the claimed invention without undue experimentation and respectfully request withdrawal of the 112 rejection.


Claims 44, 45, 59, and 60 were rejected under 35 U.S.C. §103(a) as being unpatentable over Schultz et al. (US Patent Publication No. 2003/0082575) or Chin et al. (the ‘049 reference) in view of Spetea et al (1997 Neuropeptides 31:483-488). Applicants respectfully traverse this rejection. Claim 44 has been amended to recite that the 4HB polypeptide has a para-acetyl-phenylalanine. The combination of references simply do not teach the claimed 4HB polypeptides with increased agonist activity. The present application contains examples that show the production of 4HB polypeptides, and the present specification clearly teaches specific amino acid positions to use for selector codon placement. It is therefore respectfully requested that present claims be allowed.

Conclusion

For the reasons given above, and the amendments made herein, it is respectfully submitted that all rejections and objections have been traversed and/or overcome and that the application is now in condition for allowance. If Examiner finds the present claims *not* to be allowable, Applicants hereby respectfully request a telephone interview at Examiner’s convenience to discuss the application and amendments further. Applicants may be reached at 858-875-2466. Reconsideration and allowance of the claims is respectfully requested.

Although Applicant believes that no additional fees are due with this submission, the Commissioner is hereby authorized to charge any additional fees or credit any overpayment associated with this submission to Deposit Account No. 50-3417.

Respectfully submitted,


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